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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/807,979

03/24/2004

Assaf Govari

BIO-5044

4469

27777 7590 05/11/2009  
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EXAMINER

PEFFLEY, MICHAEL F

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

05/11/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/807,979	<b>Applicant(s)</b> GOVARI, ASSAF	
	<b>Examiner</b> Michael Peffley	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/8/08; 7/8/08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

In view of the Appeal Brief filed on November 3, 2008, PROSECUTION IS  
HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the  
following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply  
under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed  
by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and  
appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth  
in 37 CFR 41.20 have been increased since they were previously paid, then appellant  
must pay the difference between the increased fees and the amount previously paid.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all  
obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley  
(5,630,837) in view of the teaching of Moore et al (6,245,020).

Crowley discloses an acoustic ablation catheter comprising an ultrasound array  
(502) arranged around the longitudinal axis at the distal portion of the device. The array  
may operate as a phased array (see col. 4, lines 59-67) to apply ablating energy to  
tissue, and the phased array may be used to control the energy profile in a desired

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manner (column 5, lines 1-23). Also, Crowley specifically disclose the use of a reflecting shield (612 – Figure 13) to provide energy in a range of approximately 180 degrees. Thus, Crowley provides two mechanisms to control the ablation energy profile delivered to tissue: phase control to target specific areas/profiles and a reflector to limit the angular range of the delivered energy. The only feature not expressly taught by Crowley is the use of between about 32 and 64 transducers.

The particular number of transducers being used is deemed to be an obvious design consideration for the skilled artisan. Applicant's specification indicates that it is not necessary to have between 32 and 64 transducers (see para. 0033 of the printed publication). Moreover, it is generally known to provide phased arrays having 32 elements as fairly taught by Moore et al (col. 19, lines 4-14). Moore et al also disclose a circumferentially arranged array of transducers and specifically teach the use of 32 elements.

To have provided the Crowley device with an array of 32 or more transducer elements making up the array would have been an obvious design consideration for one of ordinary skill in the art, particularly since Moore et al fairly teach that it is generally known to use an array of 32 transducers in a circumferentially arranged phased transducer array.

Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crowley ('837) and Moore et al ('020) as applied to claim 1 above, and further in view of Diederich et al (6,117,101).

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The combination of the Moore et al teaching with the Crowley device has been addressed previously. Crowley disclose the use of mapping electrodes and ultrasound imaging for identifying tissue to be treated, but fail to specifically indicate that the array is activated in response to the determination of tissue. It is intuitive that the determination of tissue, specifically targeted tissue, would be used to control the delivery of energy so as to not treat non-targeted tissue areas.

Diederich et al disclose another catheter ablation device that may employ an ultrasound array for providing ablative energy to tissue. Diederich et al also specifically disclose embodiments which limit or control the ablative energy to being delivered at specific azimuth ranges (col. 32, lines 52-63 as well as Figure 18a, col. 39, lines 38+). Additionally, Diederich et al teach that it is known to identify (i.e. determine) tissue and to control the energy delivery based on tissue sensing (see flowchart of Figure 9). Column 22, lines 15-22 disclose the use of a controller with the monitoring circuitry used to control ablation output based on sensed tissue conditions.

To have provided the Crowley device, as modified by the teaching of Moore et al, with a controller to control the delivery of ablation energy based on tissue sensing and identifying would have been an obvious modification for one of ordinary skill in the art, particularly since Diederich et al teach that it is known to provide such a controller to control the delivery of ablation energy based on sensed tissue in an analogous system.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Peffley whose telephone number is (571) 272-4770. The examiner can normally be reached on Mon-Fri from 7am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Peffley/  
Primary Examiner, Art Unit 3739

/mp/  
May 7, 2009

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

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/Linda C Dvorak/

Supervisory Patent Examiner, Art Unit 3739